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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,538	06/10/2002	Thomas N. Masters	38151/203996	6926

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ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
TRAVERS, RUSSELL S	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,538	MASTERS, THOMAS N.	
	Examiner	Art Unit	
	Russell Travers, J.D.,Ph.D	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment and information disclosure statement filed June 29, 2004 has been received and entered into the file.

Applicant's arguments filed June 29, 2004 have been fully considered but they are not deemed to be persuasive.

Claims 6-7 and 9-10 are presented for examination.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 6-7 and 9-10 are rejected under 35 U.S.C. § 103 as being unpatentable over Raymond , Jurado et al and Massoudy et al, for reasons of record as set forth in the office action filed August 4, 2003.

RESPONSE TO ARGUMENTS

Examiner finds those arguments presented in the response filed June 29, 2004 unconvincing.

First to the rebuttal based on the Raymond teaching. Examiner notes the instant claims read on solutions **comprising** various active ingredients, carriers and excipients useful for the same purpose, thereby obviating the use of fewer ingredients employed for the same purpose. If some unexpected benefit resides in fewer ingredients Applicant has the burden to illustrate such benefits. As stated above, active ingredients residing in the prior, unclaimed in the presented invention, are, absent a showing of unexpected benefit are simply a "make weight".

Massoudy et al teach those ischemia protecting benefits residing employing CsA at 0.8 parts per million (PPM), a level physiologically indistinguishable for that averred by the Griffiths et al article. These levels of CsA employed by Massoudy et al are shown to provide effective protection from those forces mediating damage to the excised heart during that time period between removal and implantation. Examiner notes the Massoudy et al teaching employs an external heart work (EHW) standard to evaluating the effectiveness

of the protective regimens. This employment of physical evaluation standards would be seen as erosive to those rebuttal arguments based on the Griffiths et al teaching. Attention is directed to Griffiths et al (page 1468, column 2, paragraph 2) wherein Griffiths et al set forth the limitations of their study employing a limited biochemical marker. Griffiths et al admit the "ability of CyS to restore completely the ATP/ATP ratio and the AMP levels to pre-ischemic values after 30 min ischemia is not entirely paralleled by its effect on functional recovery". Thus, having not investigated the actual effect of the CsA therapy on the actual EHW possible upon reperfusion, the proposed negative teaching of Griffiths et al has no probative value.. Examiner notes the negative teaching of Griffiths et al also is directed to CsA, not cyclosporin compounds generally as herein constructively averred. The instant claims are not directed to CsA, thus, a "teaching away" based rebuttal argument for claims not so limited , is moot.

The Massoudy et al teaching was published four (4) years after the Griffiths et al article, and would, thus, be seen as superceding Griffiths et al and setting forth the state of the art. Examiner additionally notes the Massoudy et al teaching employing medicament levels four fold greater than the Griffiths et al 0.2 micro molar treatment, and very similar to the 1.0 micro molar dosage levels taught as ineffective. Examiner notes this proposed negative teaching would should negatively impact those instant claimed inventions employing CsA.

Absent the underlying teaching of Jurado et al those specific time frames employed are difficult to ascertain Jurado et al teachings are employed to illustrate the

benefits residing in short term CsA exposure of hearts employed in transplantation at levels of 5 parts per million; as herein claimed.

Rebuttal arguments based on the employment of apoptosis language are unconvincing. As stated before, Applicant□s amendments present a distinction that fails to alter the presented inventions scope. The therapeutic goal recited in the prior art, and that herein envisioned, are indistinguishable. The instant arguments suggest the claims are directed to effecting a biochemical pathway with an old and well known compound. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art dose not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and

well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Applicants aver unexpected benefits residing in the claimed subject matter, yet fail to fails to set forth evidence substantiating this belief. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants is not reasonably commensurate in scope with the instant claims, or distinguishes the instant claims from those therapies taught in the Examiner cited prior art. Absent claims commensurate with the showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

It is well known by the skilled artisan that carriers and excipients are employed to enhance the activity of active ingredients. Thus, the skilled artisan would expect conventional excipients and carriers to be useful concomitantly, absent information to the contrary. The instant carriers and excipients are not employed concomitantly in the prior art, thus only obviate their concomitant use.

Applicant's attention is drawn to In re Graf, 145 USPQ 197 (CCPA 1965) and In re Finsterwalder, 168 USPQ 530 (CCPA 1971) where the court ruled that when a substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance.

Examiner would favorably consider claims directed to those medicaments providing unexpected therapeutic benefits, as averred herein.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D.,Ph.D whose telephone number is 571-272-0631. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Travers, J.D, Ph.D.
Primary Examiner
Art Unit 1617